

TECHNICAL STANDARDS AND REQUIREMENTS FOR THE REGISTRATION, OPERATION AND MAINTENANCE OF CLINICAL LABORATORIES IN THE PHILIPPINES

KPL BUREAU ORDER NO. 4, January 15, 1990

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SECTION 1. Title . — These standards shall be known as "Technical Standards and Requirements for the Registration, Operation and Maintenance of Clinical Laboratories in the Philippines".

SECTION 2. Authority . — These technical standards are issued to implement R.A. 4688 (Clinical Laboratory Law) with its Revised Rules and Regulations (A.O. 49-B, s. 1988) consistent with E.O. 119 (Reorganization Act of the Ministry of Health).

SECTION 3. Purpose . — These standards are promulgated to protect and promote the health of the people by preventing the operation of substandard, improperly managed and inadequately supported clinical laboratories and by improving the quality of performance of clinical laboratory examinations as well as to enable the Bureau of Research and Laboratories, Department of Health to evaluate compliance with such technical standards as requirements for the issuance of a license.

SECTION 4. Scope . — The requirements embodied herein shall apply to primary, secondary and tertiary hospital clinical laboratories and free-standing (non-hospital) clinical laboratories.

SECTION 5. Classification . — Clinical laboratories are classified according to:

1. Function — It may perform any or all of the following:

1.1. Clinical Pathology includes clinical chemistry, hematology, microbiology, parasitology, mycology, clinical microscopy, immunology and serology, immunochemistry and blood banking, radioisotope analysis and laboratory endocrinology and similar discipline.

1.2. Anatomic Pathology includes surgical pathology, histochemistry, immunopathology, cytology and post-mortem examinations.

1.3. Forensic Pathology includes all medico-legal examinations.

2. Institutional Character — They may either be a:

2.1. Hospital laboratory that operates within a hospital, or

2.2. Free-standing (non-hospital) laboratory that operate on its own or as part of an activity other than a hospital.

3. Service extent and level — They are either (1) primary; (2) secondary; or (3) tertiary category depending on the range of laboratory examinations they perform and the presence of certain manpower, materials and facilities required.

SECTION 6. Service Capabilities . — The minimum services required of each respective category of hospital and

free-standing clinical laboratories shall be:

Primary Category

1. Routine Hematology — Complete Blood Count (CBC) which includes:

- Hemoglobin Mass Concentration
- Erythrocyte Volume Fraction (Hematocrit)
- Leucocyte Number Concentration (WBC)
- Leucocyte Type Number Fraction (Differential Count)

2. Routine Urinalysis

3. Routine Fecalalysis

4. Gram Staining

Secondary Category

1. Routine Hematology, Urinalysis, Fecalalysis and Gram Staining

2. Routine Chemistry

- Blood Glucose Substance Concentration
- Urea Substance Concentration
- Uric Acid Substance Concentration
- Creatinine Substance Concentration
- Cholesterol Substance Concentration
- Total Protein Mass Concentration

Tertiary Category

1. Routine Hematology, Urinalysis, Fecalalysis and Gram Staining

2. Routine Chemistry

3. Blood Typing and Cross-matching, donor selection and blood collection for transfusion

4. Special Chemistry

5. Special Hematology

6. Culture and Sensitivity for Bacteria

SECTION 7. Standards . — The following technical standards and requirements are to be complied with by the following corresponding category of clinical laboratories:

I

Head

The clinical laboratory shall be managed and supervised by a physician who is licensed and duly registered with the Board of Medicine (PRC), qualified in laboratory medicine and duly authorized by the Undersecretary of Health for Standards and Regulation or his duly authorized representative.

1. Depending on the category, the following shall be the requirements:

Primary Category:

1. Free standing Clinical Laboratory shall be managed by a licensed physician, certified by the Philippine Board of Pathology in either Anatomic or Clinical Pathology or both.
2. Hospital Clinical Laboratory (in areas where Pathologists are not available) may be managed by a certified pathologist or a physician with training at least three (3) months in laboratory medicine, quality control and laboratory management and authorized by the Bureau of Research and Laboratories.

Secondary Category

1. Hospital and free-standing clinical laboratories shall be managed by a certified pathologist.
2. Hospital clinical laboratory, in areas where there are insufficient pathologists, may be managed by a physician with training of at least three (3) months in laboratory medicine, quality control and laboratory management and authorized by the Bureau of Research and Laboratories.

Tertiary Category

1. Hospital and free-standing clinical laboratories shall be managed by a certified pathologist.
2. A certified pathologist may be authorized to manage or supervise or be an Associate in not more than four (4) clinical laboratories/blood banks.

A physician who is not certified pathologist may be authorized under Sec. 7, 1-2 of A.O. #49-B, s. 1988, to manage/supervise only one (1) hospital laboratory.

II

Personnel

The clinical laboratory shall have adequate staff or qualified and trained personnel with at during hours of laboratory operation, the number of which is dependent on the workload.

1. Work assignment shall be consistent with the qualification of the employee. Emergency laboratory procedures, (i.e. arterial puncture or potentially hazardous procedures) shall be performed only a qualified medical staff or duly authorized personnel.
2. All personnel including the Head, belonging to the professional group shall maintain a current license issued by the Philippine Regulation Commission, Philippine Board of Pathology or an authority from the Bureau of Research and Laboratories.

III

Physical Facilities

The clinical laboratory shall be well- ventilated, lighted, clean and safe, the physical space sufficient to accommodate its activities.

1. The technical working space for all categories of clinical laboratories both hospital and free-standing shall have a minimum area of:

Category Space in sq. m.

Primary 10

Secondary 20

Tertiary 60

2. It should be well- ventilated, adequately lighted, safe and a clean place to work in with an adequate water

supply.

IV

Equipment

There shall be provision for a sufficient number and types of necessary equipment/instruments in order to undertake the different types of activities or range of laboratory examinations and the volume of examinations to be done and that they shall comply with safety requirements.

1. Hospital and free-standing clinical laboratories shall have the following minimum requirements:

Primary Category

Equipment/Instruments

- Burner/alcohol lamp
- Centrifuge
- Hemacytometer
- Hemoglobinometer
- Hematocrit centrifuge
- Microscope
- Urinometer

Secondary Category

Equipment/Instruments

- Burner/alcohol lamp
- Centrifuge
- Hemacytometer
- Hemoglobinometer
- Hematocrit centrifuge
- Microscope
- Urinometer
- Refrigerator
- Serofuge
- Photometer
- Water bath

Tertiary Category

Equipment/Instruments

- Burner/alcohol lamp
- Centrifuge
- Hemacytometer
- Hemoglobinometer
- Hematocrit centrifuge
- Microscope
- Urinometer
- Blood Counter, differential
- Refrigerator
- Serofuge
- Photometer

Timer, interval
Water bath
Incubator, 35°C + 2°C
Stethoscope
Trip balance
Rotator
Weighing Scale
Autoclave (in lab/CSR)
Drying oven

For Anatomic Pathology Services:

Microtome with knife
Paraffin oven
Flotation bath

2. For other laboratory examinations being performed, the appropriate equipment necessary for performing such procedures should be available.

3. Provisions for the proper functioning and maintenance of the equipment should be made to ensure quality performance at all times.

V

Glasswares/Reagents/ Supplies

Hospital and free-standing clinical laboratories, primary, secondary and tertiary categories shall prove the glasswares, reagents and supplies necessary to undertake the required services.

VI

Quality Control

All clinical laboratories shall have a program of Quality Control that is sufficiently comprehensive to ensure that reagents, equipment and methods function as expected thus help and upgrade the standards of laboratory practices.

1. There shall be provisions for an internal and external Quality Control Program.

1.1. Internal Quality Control Program

1.1.1. There should be proper selection and maintenance of appropriate personnel.

1.1.2. There should be program for the proper maintenance and monitoring of status of all equipment.

1.1.3. The program must provide for specific and sensitive methods and appropriate standards.

1.1.4. There shall be a program to detect deviations from proper laboratory practices/conditions with the use of quality control materials.

1.2. External Quality Control Program

1.2.1. All clinical laboratories shall participate promptly in the Quality Assurance Program of the BRL whenever samples for proficiency testing are received.

1.2.2. The Satisfactory performance in the proficiency testing shall be one of the criteria for the renewal of license.

1.2.3. Any refusal to participate in the Quality Assurance Program of the BRL will be the basis for suspension/revocation of the license of the laboratory.

VII

Reporting

Laboratory requests shall be construed as consultation between the requesting physician and the pathologist of the laboratory and as such should be properly released.

1. The following shall be observed:

1.1. All laboratory reports on various examinations of specimens shall bear the name of the pathologist or his associate.

1.2. No person in the clinical laboratory shall issue a report, orally or in writing, whole or portions thereof without a directive from the pathologist or his authorized associate and only to the requesting physician or his authorized representative except in emergencies when the results may be released as authorized by the pathologist.

2. There shall be provision for an effective method of communication to ensure prompt and reliable reporting.

VIII

Recording

There should be provisions of accurate recording to ensure proper care of patients, the production of quality results and for medico-legal purposes.

1. There must be maintained in the clinical laboratory an adequate and effective system of recording all requests and reports of all human specimens submitted and examined.

2. To prevent erroneous reporting and permit ready identification and retrieving, there should be provisions for filing, storage and accession number in addition to patient's personal information.

3. All reports in the clinical laboratory shall be kept in file for at least one (1) year provided the original report is on file in the patient's medical records.

4. Records of anatomic and forensic pathology should be kept permanently in the laboratory.

There should be a coded system using patients personal and clinical data.

IX

Laboratory Fees

The laboratory and professional fees to be charged for a clinical laboratory examination shall be the prevailing rates.

1. The rates shall be within the range of the usual fees prevailing at the time and the particular place taking into consideration cost of production and quality control of various laboratory procedures.

2. Professional services rendered to the patient in the performance of the special procedures or examination shall be treated separately and not included in the laboratory fee.

This Bureau Order takes effect immediately.

Adopted: 15 Jan. 1990

(SGD.) TOMAS P. MARAMBA, JR.
Officer-In-Charge

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